NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LORY D'ADDARIO AND PETER D'ADDARIO, Plaintiffs, v. **JOHNSON & JOHNSON, *et al.,*** Defendants.	Civil Action No. 19-15627 (ZNQ) (TJB) **OPINION**

QURAISHI, District Judge

THIS MATTER comes before the Court upon a Motion to Dismiss filed by Defendants Johnson & Johnson, Mentor Worldwide, LLC ("Mentor"), and Ethicon, Inc. (collectively, "Defendants") (ECF No. 61). In support of their Motion, Defendants filed a Moving Brief. ("Moving Br.", ECF No. 61-1.) Plaintiffs Lory and Peter D'Addario (collectively, "Plaintiffs") filed a brief in Opposition to Defendants' Motion ("Opp'n", ECF No. 62), to which Defendants replied ("Reply", ECF No. 63).

The Court has carefully considered the parties' submissions and decides the Motion without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, the Court will GRANT the Motion with respect to Count I(b) and (e) and DENY the Motion with respect to Count I(a), (c), (d), and Count II.

I. BACKGROUND AND PROCEDURAL HISTORY

Plaintiffs initiated this action on July 19, 2019. (ECF No. 1.) On July 31, 2020, Plaintiffs filed an Amended Complaint (ECF No. 32) which Defendants moved to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) (ECF No. 36). On March 31, 2021, the Court granted Defendants' motion and dismissed the Amended Complaint without prejudice. *D'Addario v. Johnson & Johnson et al.,* Civ. No. 19-15627, 2021 WL 1214896, at *8 (D.N.J. Mar. 31, 2021). In its Opinion, the Court afforded Plaintiffs one final opportunity to amend and re-file their pleading. (*Id.*) Plaintiffs subsequently filed their Second Amended Complaint—now the operative pleading—on April 20, 2021. ("SAC", ECF No. 59.)

The SAC asserts two counts against Defendants stemming from breast implants that allegedly "caused Plaintiff Lory D'Addario to develop Breast Implant-Associated Large Cell Lymphoma ("BIA-ALCL")—a rare form of cancer—as a direct and proximate result of violations of FDA laws, regulations and requirements applicable to manufacturing, warnings and post-marketing requirements." (*Id.* ¶ 1.)

The relevant breast implants include both Mentor's MemoryShape textured breast implants and Mentor's CPX4 tissue expanders that were inserted in Plaintiff to prepare her for the permanent MemoryShape implants (together, "the Siltex implants").[1] Defendants design, manufacture, market, label, and distribute the Siltex implants. (*Id.* ¶ 238.) The Siltex implants are "textured." (*Id.* ¶ 1.) The SAC describes the process used to obtain this texture:

> Mentor uses negative-contact polyurethane foam to stamp its Siltex breast implant surfaces. Specifically, a chuck is dipped into uncured silicone to form the shell after which the uncured silicone shell is

[1] In the prior two iterations of the Complaint, the product at issue was limited to the MemoryShape permanent breast implants. For the first time in this suit, the SAC adds allegations with respect to the temporary tissue expanders. Defendants object to this expansion on the basis that the relevant statute of limitations has run, but for the reasons set forth below, the Court will permit the tissue expander subject matter to be added via the SAC.

> pressed into polyurethane foam to imprint pores measuring 70 to 150 mm in diameter and 40 to 100 mm in height.

(*Id.* ¶ 242.) According to the SAC, this process, however, leaves free material on the surface of the Siltex implants in the form of "debris," "fragments," and/or "particles" (hereinafter "debris"). (*Id.* ¶¶ 3, 106.) The debris may be comprised of silica or polyurethane. (*Id.*) Plaintiff's exposure to this debris caused chronic inflammation and ultimately, the development of ALCL. (*Id.* ¶ 111.)

Plaintiffs allege that following the PMA for the Mentor Breast Implants, Defendants failed to comply with numerous FDA post-approval reporting requirements. For example, Plaintiffs assert that Defendants "failed to report adverse events, including incidences of BIA-ALCL, from the post-market approval studies commissioned [by the FDA] as part of the Siltex implant's PMA approval." (*Id.* ¶ 99.) With respect to these post-market approval studies, Plaintiffs maintain that "Mentor failed to properly perform the six studies, failed to follow-up with enough participants, and did not fully report adverse events. Accordingly, the information which the FDA was seeking regarding adverse events and device failures was never gathered." (*Id.* ¶ 43.) Plaintiffs note that "time is of the essence for Mentor when reporting adverse events, especially, but not limited to, those adverse events indicating an association between its product and breast cancer, Anaplastic Large-Cell Lymphoma ("ALCL") and/or BIA-ALCL." (*Id.* ¶ 85.) "Delayed reporting prevents the healthcare community and the public from learning of risks which must inevitably play a part in their decision-making, by both physicians and consumers, regarding treatments and procedures, and thereby expose[s] countless additional women to potential harm." (*Id.* ¶ 86.)

In July 2015, after a breast cancer diagnosis and subsequent mastectomy, D'Addario underwent breast reconstructive surgery and received Mentor Breast Implants. (*Id.* ¶¶ 47–48.) At the time Mentor CPX4 tissue expanders were placed into D'Addario's body in preparation for the permanent implants, "she was not advised, nor did she have any independent knowledge, that the

tissue expanders were associated with or could cause BIA-ALCL" (*id.* ¶ 45) and, according to Plaintiff, had she "been advised that implantation was associated with even the slightest risk of developing ALCL and/or BIA-ALCL she would not have proceeded with implantation of the SILTEX implants" (*id.* ¶ 53).

In July 2017, Mrs. D'Addario tested positive for BIA-ALCL. (*Id*. ¶ 55.) Following diagnosis and treatment, Mrs. D'Addario suffered pain, swelling, and embarrassment (*id*. ¶ 59), and in August 2017, she underwent implant removal and total capsulectomy (*Id*. ¶ 56).

According to Plaintiffs, the breast implants that "Mrs. D'Addario received were not the breast implants and expanders approved by the FDA as they contained manufacturing debris." (*Id*. ¶ 257.) Defendants failed to adhere to federal specifications and thus manufactured defective products." (*Id*. ¶ 258.) The SAC maintains that Defendants' manufacturing deficiencies included: manufacturing their textured breast implants in a non-conforming manner, failing to sterilize the implants in conformance with the PMA, failing to satisfy the study and follow-up requirements set forth in the PMA and other federal requirements, failing to maintain procedures to prevent contamination of equipment or products, and failing to timely and accurately submit adverse event reports on the occurrences of BIA-ALCL. (*Id.*)

The SAC asserts two Counts against Defendants. Plaintiffs assert Count One for violation of the Connecticut Products Liability Act ("CPLA"), Conn. Gen. Stat. §§ 52-572m, et seq., under manufacturing defect, breach of implied warranties, failure to provide warnings, negligent manufacturing, and negligent misrepresentation theories. (*Id*. ¶¶ 241–323.) Plaintiffs bring Count Two for loss of consortium. (*Id*. ¶¶ 324–28.)

II. LEGAL STANDARD

District courts undertake a three-part analysis when considering a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). "First, the court must 'tak[e] note of the elements a plaintiff must plead to state a claim.'" *Id*. (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)) (alteration in original). Second, the court must accept as true all of the plaintiff's well-pled factual allegations and "construe the complaint in the light most favorable to the plaintiff." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quotation omitted). In doing so, the court is free to ignore legal conclusions or factually unsupported accusations that merely state "the-defendant-unlawfully-harmed-me." *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "[M]ere restatements of the elements of [a] claim[] . . . are not entitled to the assumption of truth." *Burtch v. Milberg Factors, Inc*., 662 F.3d 212, 224 (3d Cir. 2011) (alterations in original) (quotation omitted). Finally, the court must determine whether "the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679). "The defendant bears the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005) (citation omitted).

"Rule 12 prohibits the court from considering matters outside the pleadings in ruling on a motion to dismiss for failure to state a claim . . . and a court's consideration of matters outside the pleadings converts the motion to a motion for summary judgment." *Kimbugwe v. United States*, Civ. No. 12-7940, 2014 WL 6667959, at *3 (D.N.J. Nov. 24, 2014). "[A]n exception to the general rule is that a document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment." *In re Burlington Coat*

Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997) (emphasis omitted) (internal quotation marks omitted).

III. DISCUSSION

A. FEDERAL PREEMPTION

It is undisputed that the Mentor Breast Implants are a Class III medical device approved by the FDA under the premarket approval process outlined by the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). (SAC ¶ 29.) "Before marketing a Class III medical device, the manufacturer must submit a PMA application that the FDA can grant 'only after it determines that a device offers a reasonable assurance of safety and effectiveness.'" *In re Allergan Biocell Textured Breast Implant Prods*. Liability Litig., Civ. No. 19-2921, 2021 WL 1050910, at *7 (D.N.J. Mar. 19, 2021) (quoting *Riegel v. Medtronic, Inc*., 552 U.S. 312, 323 (2008) (citing 21 U.S.C. § 360e(d))). "A state law product liability or tort claim relating to a medical device may be expressly or impliedly preempted by the MDA," which "contains a broad express preemption provision." *Id*. (quoting *Shirker v. Smith & Nephew, PLC*, 885 F.3d 760. 767 (3d Cir. 2018)). "The MDA provides that no State 'may establish or continue in effect with respect to a device . . . any requirement relating to safety or effectiveness that is different from, or in addition to, federal requirements." *Riegel*, 552 U.S. at 328 (quoting 21 U.S.C. § 360k(a)).

The Supreme Court has recognized, however, a narrow exception for a "'parallel' claim, e.g., 'a damages remedy for claims premised on a violation of FDA regulations.'" *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 600 (D.N.J. 2015) (quoting *Riegel*, 552 U.S. at 330). To determine whether the MDA expressly preempts a state claim under § 360k(a), courts consider (I) whether the FDA has established "requirements" applicable to the specific device at issue; and if so, (2) whether the plaintiff's claims are based on state requirements that are "different from, or in addition to," the federal ones and that "relate to safety and effectiveness." *Shirker*, 885

F.3d at 771 (citing *Riegel*, 552 U.S. at 321-22). If the answer is yes to both questions, the state claim is preempted. *Id*. "If, instead, the answer to the second question is no, then the state duties in such a case parallel, rather than add to, federal requirements, and the claims are not preempted." *Id*. (citation omitted) (internal quotation marks omitted).

Even if a state-law claim is not expressly preempted, it may be impliedly preempted under § 337(a). Under the MDA, all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). "[T]he Federal Government rather than private litigants . . . are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 349 n.4 (2001). To that end, the *Buckman* Court held that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives" and are impliedly preempted by the MDA. *Id*. at 350.

Ultimately, where a state-law claim for violating a state-law duty "parallels" a federal-law duty under the MDA, the MDA will not preempt the state-law claim. *Riegel*, 552 U.S. at 330. It is not enough to contend that a state law parallels federal law generally. Plaintiffs must also allege a link between a product's deviation from an FDA requirement and the alleged injury. *Clements*, 111 F. Supp. 3d at 598; *see Simoneau v. Stryker Corp*., Civ. No. 13-1200, 2014 WL 1289426, at *10 (D. Conn. Mar. 31, 2014) (dismissing a plaintiff's misbranding, failure to warn, and failure to report claims for failure to link her injury to a violation of an FDA requirement).

While Mentor's MemoryShape breast implants are Class III medical devices subject to PMA and federal requirements, Mentor's CPX4 tissue expanders are non-PMA devices, and are sold through the § 510(k) process which does not trigger preemption. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996).

The Court considers Plaintiffs' claims within the foregoing legal framework.

B. COUNT I—VIOLATION OF THE CONNECTICUT PRODUCT LIABILITY ACT

Count I of the SAC alleges multiple violations of the CPLA: manufacturing defects, breach of implied warranty, failure to provide warnings, negligent manufacturing, and negligent misrepresentation. (SAC ¶¶ 241–323.) Under Connecticut law, the CPLA is the "exclusive remedy for claims falling within its scope." *Winslow v. Lewis-Shepard, Inc.*, 212 Conn. 462, 471 (1989). A plaintiff cannot assert common law causes of action for product liability. *Id.*; *see also Densberger v. United Techs. Corp.*, 297 F.3d 66, 70 (2d Cir. 2002) (The CPLA "bars separate common law causes of action in product liability cases"). "In addition, a product liability claim is defined broadly to include, but not be limited to, all actions based on '[s]trict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation or nondisclosure, whether negligent or innocent.'" *Gerrity v. R.J. Reynolds Tobacco Co.,* 263 Conn. 120, 127 (2003) (quoting CONN. GEN. STAT. § 52-572m(b)). Lastly, "the CPLA excludes all claims for personal injury caused by the warnings, instructions, marketing, packaging or labeling of any product." *Johannsen v. Zimmer, Inc.*, Civ. No. 00-2270, 2005 WL 756509, at *10 (D. Conn. Mar. 31, 2005) (internal quotation marks and citations omitted) (excluding a plaintiff's fraud claim because it arose "out of his personal injuries as allegedly caused by inaccurate or fraudulent marketing, packaging or labeling.").

1. Manufacturing Defect (Count I(A)) and Negligent Manufacturing (Count I(D))

Under the CPLA, in order to prove a strict liability claim, Plaintiffs must show that the device was "in a defective condition unreasonably dangerous to her and that this defect caused the injury for which she seeks damages." *Simoneau*, 2014 WL 1289426, at *5. Such defective

condition may be "due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions." *Id*. (internal quotation marks and citation omitted). "In order to avoid preemption on a manufacturing defect claim, [Plaintiffs] must allege that [the] device was not manufactured in conformance with the specifications approved by the FDA." *Norman v. Bayer Corp*., Civ. No. 16-253, 2016 WL 4007547, at *2 (D. Conn. July 26, 2016).

"To sufficiently plead a manufacturing defect claim, [p]laintiffs must allege [defendants] 'deviated from a particular premarket approval or other FDA requirement applicable to the class III medical device.'" *D'Addario*, 2021 WL 1214896, at *8 (quoting *In re Allergan*, Civ. No. 19-2921, 2021 WL 1050910, at *20 (D.N.J. Mar. 19, 2021). Moreover, Plaintiffs "cannot simply demonstrate a defect or a malfunction and rely on *res ipso loquitur* to suggest only . . . that the thing speaks for itself." *Id*. (quoting *Nunn v. Mentor Worldwide, LLC*, Civ. No. 19-56391, 2021 WL 406304, at *2 (9th Cir. Feb. 5, 2021)).

As discussed above, Plaintiffs may bring state law tort claims against Defendants that "parallel" a violation of FDA regulations. Nevertheless, courts "use the *Iqbal/Twombly* standard to determine whether [p]laintiffs have stated a plausible claim" for manufacturing defect. *D'Addario*, 2021 WL 1214896, at *4; *see also Morton v. Allergan, Inc*., Civ. No. 14-1312, 2015 WL 12839493, at *4 (D.N.J. Apr. 2, 2015) ("[i]n short, a 'parallel claim,' like any other, is subject to the pleading standards of *Twombly*."). "Plaintiffs must nudge the claim across the line from conceivable or speculative to plausible. Allegations that are merely consistent with a defendant's liability stop short of that line." *Brooks,* 985 F.3d at 1281 (citations omitted). Courts have emphasized that a plaintiff "cannot simply incant the magic words [the defendant manufacturer] violated FDA regulations in order to avoid preemption." *Morton*, 2015 WL 12839493, at *4 (citations omitted). "Rather, the plaintiff must plead facts showing action or inaction in [the]

defendants' efforts to take part in the PMA process or implement its results." *Clements*, 111 F. Supp. 3d at 599 (alteration in original) (citation omitted).

Here, Plaintiffs allege that Defendants violated several of the FDA's Current Good Manufacturing Practice regulations ("CGMPs") governing the manufacturing of medical devices.

In their Motion, Defendants argue that Plaintiffs "failed to demonstrate how Mentor's manufacturing processes deviated from the manufacturing processes approved by the FDA" and that "Plaintiffs' citation to regulations alone" are not sufficient to overcome preemption. (Moving Br. at 6.) Moreover, "despite this Court's prior Orders, many of Plaintiff[s'] manufacturing defect allegations are, in reality, claims for design defect." (*Id.* at 7.) Lastly, the manufacturing defect claim fails because it does not claim a manufacturing defect with respect to Plaintiffs' implants but rather claims a defect in the manufacturing process itself. (*Id.*)

The SAC specifically pleads that Defendants failed to sterilize their MemoryShape implants in conformance with the PMA (SAC ¶ 258) and failed to remove debris from the silicone shells of the Siltex implants pursuant to 21 C.F.R. § 820.70(h).[2] (*Id.* ¶¶ 104–12). This manufacturing defect caused an uncontrolled and unintended increase in the surface area of the implants and expanders and left residual manufacturing material on the Siltex surfaces, which led directly to Plaintiffs' harm.[3] (*Id.* ¶ 135.) Plaintiffs have therefore plausibly pled that the product was defective and that the defect existed when the product left the manufacturer's control. *Bifolck*

[2] According to Plaintiffs, Defendants deviated from the FDA's standards that require manufacturers to "ensure the removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that the amount of manufacturing material does not adversely affect the device's quality." (SAC ¶ 68) (quoting21 C.F.R. § 820.70(h)).

[3] "The unintended increase in surface area due to pores and interstices and the unintended residual debris left on the surface caused or contributed to the proliferation of T-cells." (SAC ¶ 135.) "In addition, Mentor's uncontrolled and un-validated texturing process caused or contributed to a chronic inflammatory response in patients' bodies which caused or contributed to the development of ALCL." (*Id.*)

v. Philip Morris, Inc., 324 Conn. 402, 434 (2016). Accordingly, the Court concludes that the SAC has sufficiently alleged that the implants and tissue expanders contained a manufacturing defect.

The SAC also alleges that Defendants negligently manufactured the Siltex implants by "not controlling the texturing process leaving residual silicone and polyurethane particles, debris and fragments from the textured elastomer shell on the implant surface." (SAC ¶ 306.) With respect to these allegations, the Court reaches the same conclusions regarding preemption that it reached with respect to the related allegations under strict liability, and for the same reasons outlined above. *Simoneau*, 2014 WL 1289426, at *12. "First, negligent manufacturing is not preempted, because to the extent such negligence is premised on a violation of FDA requirements, the state common law duty parallels the federal requirement." *Id.*; *see also Bass v. Stryker Corp.*, 669 F.3d 501, 515 (5th Cir. 2012), (negligent manufacturing claim not preempted); *Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir.2010) (same); *Gelber v. Stryker Corp.*, 788 F.Supp.2d 145, 155-60 (S.D.N.Y. 2011) (same). Accordingly, the Court concludes that Plaintiffs' negligent manufacturing claims as to the MemoryShape are also not preempted. As noted above, claims pertaining to the tissue expanders are not subject to preemption. The portion of Defendants' Motion seeking to dismiss Counts I(A) and I(D) will therefore be denied.

2. Breach of Implied Warranty (Count I(B)) and Negligent Misrepresentation (Count I(E))

Within their CPLA claim, Plaintiffs argue that Defendants breached their implied warranty of merchantability, implied warranty of fitness for a particular purpose, and the Connecticut Unfair Trade Practices Act ("CUTPA").[4] (SAC ¶ 268.) Courts have held that "because the CPLA is

[4] In its prior decision, the Court unambiguously dismissed Plaintiffs' breach of warranty claim under CUTPA on the basis that it was barred by the CPLA's exclusivity provision. *D'Addario v. Johnson & Johnson*, 2022 WL 3546750, at *2–3 (D.N.J. June 30, 2020). The claim, however, remains in the SAC unchanged. (SAC ¶ 268.) Defendants drew this to the Court's attention in their moving papers (Moving Br. at 21, n.7), but Plaintiffs did not respond. To the extent that Plaintiffs are attempting to relitigate this issue, the law of the case doctrine prevents them from doing so. *Hayman Cash Register Co. v. Sarokin*, 669 F.2d 162, 165 (3d Cir. 1981). There are certain exceptions to the law of

silent as to the elements of a cause of action for breach of warranty," plaintiffs may rely on the Connecticut Uniform Commercial Code, Title 42a of the Connecticut General Statutes ("CUCC"). *Walters v. Howmedica Osteonics Corp*., 676 F.Supp.2d 44, 55 (D. Conn. 2009); *Johnson v. Sears Roebuck & Co*., Civ. No. 05-139, 2007 WL 2491897, at *4 (D. Conn. Aug. 29, 2007). "The CUCC defines implied warranties in two provisions. Connecticut General Statute section 42a-2-315 provides: '[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under section 42a-2-316 an implied warranty that the goods shall be fit for such purpose.'" *Walters*, 676 F.Supp.2d at 55 (quoting Conn. Gen. Stat. §42a-2-315). "Connecticut General Statute section 42a-2-314 provides: '[u]nless excluded or modified as provided by section 42a-2-316, a warranty that the goods shall be merchantable is implied in a contract with respect to goods of that kind.'" *Id*. (quoting Conn. Gen. Stat. §42a-2-314). "This implied warranty of merchantability 'acts as a guarantee by the seller that his goods are fit for the ordinary purposes for which they are to be used and will pass in the trade without objections.'" *Id*. (quoting *Blockhead, Inc. v. Plastic Forming Co., Inc*., 402 F.Supp. 1017, 1025 (D. Conn. 1975)).

To make out a claim for negligent misrepresentation, a plaintiff must establish (1) that the defendant made a misrepresentation of fact (2) that the defendant knew or should have known was false, (3) that the plaintiff reasonably relied on the misrepresentation and thus (4) suffered pecuniary harm. *See McNeil v. Yale Univ*., 436 F. Supp. 3d 489, 536 (D. Conn. 2020) (citing *Nazami v. Patrons Mut. Ins. Co*., 280 Conn. 619, 626, 910 A.2d 209 (2006)). Courts disagree

---

the case doctrine, but none of them apply here. *See Conery v. Niccollai*, Civ. No. 92-840, 1998 WL 34076966, at *4 (D.N.J. Feb. 2, 1998). Accordingly, the Court will again dismiss Plaintiffs' breach of warranty claim premised on CUTPA.

about whether the heightened pleading standard of Rule 9(b) applies to negligent misrepresentation claims. *See ARMOUR Capital Mgmt. LP v. SS&C Techs., Inc*., Civ. No. 17-790, 2018 WL 1368908, at *6 (D. Conn. Mar. 16, 2018) (describing the disagreement). However, courts agree that when "negligent misrepresentation is couched in fraud-like terms of known falsity," the heightened fraud pleading standard applies. *See Karazin v. Wright Med. Tech., Inc*., Civ. No. 17-823, 2018 WL 4398250, at *7 (D. Conn. Sept. 14, 2018); *ARMOUR Capital, Mgmt. LP v. SS&C Techs., Inc.*, Civ. No. 17-790, 2020 WL 64297, at *2 (D. Conn. Jan. 5, 2020).

Plaintiffs allege that Defendants breached their implied warranties by selling "defective [b]reast [i]mplants as though they ha[d] met all federal requirements." (SAC ¶ 273.) Similarly, Plaintiffs allege that Defendants "knowingly made negligent misrepresentations of fact by selling its [breast] implants that were defectively manufactured as if they were manufactured pursuant to all federal specifications." (*Id*. ¶ 315.) Plaintiffs explain that Defendants negligently misrepresented the safety of their Siltex implants because they "deliberately concealed or failed to disclose the risk of contracting BIA-ALCL by not complying with medical device reporting regulations or federal disclosure requirements imposed by the PMA." (Opp'n at 20.)

In their Motion, Defendants argue that Plaintiffs' misrepresentation and warranty claims are preempted because "while both claims are packaged as warranty and misrepresentation claims, in essence they just assert more of the same conclusory allegations that challenge the safety and effectiveness of the . . . implants."[5] (Moving Br. at 21.)

[5] Defendants acknowledge that the SAC no longer asserts a breach of express warranty claim as part of Count I(B), despite what appears to be an inadvertent usage of the word "express" at SAC paragraph 268. (Moving Br. at 21 n.8.) In an abundance of caution, however, they ask the Court to dismiss any claim for breach of express warranty. Plaintiffs did not respond in their Opposition. Having reviewed the SAC, the Court agrees that its usage of "express" was a mistaken carryover from the prior Complaint. Defendants' request will therefore denied as moot.

Here, because the Court has already determined that Plaintiffs have sufficiently pled manufacturing defect claims in III.B.i *supra*, it further finds that their breach of implied warranty claims are also viable and not preempted. *See McConologue*, 8 F. Supp. 3d at 115 (citing *Gelber v. Stryker Corp*., 788 F. Supp. 2d 145, 166 (S.D.N.Y. 2011) (finding plaintiffs' implied warranty claim not preempted as it was based on their manufacturing claim, for selling an adulterated device makes the product unfit for its ordinary purpose)); *see also Bass*, 669 F.3d at 517 ("We agree . . . that an implied warranty claim is not preempted if the plaintiff alleges that the defendant violated federal requirements and can ultimately show a causal link between the violation and the breach of the implied warranty.").

However, Plaintiffs' negligent misrepresentation claim cannot succeed because failing to disclose a risk by not complying with the reporting regulations or federal disclosure requirements does not satisfy the standard required to sufficiently claim negligent misrepresentation. *See Norman*, 2016 WL 4007547, at *6 (dismissing negligent misrepresentation claim as preempted where "plaintiff does not identify any statement that is outside what was approved by the FDA"). Moreover, Plaintiffs' negligent misrepresentation claims are indeed couched in fraud-like terms such that a heightened pleading standard applies.[6] *Herlth v. Merck & Co., Inc.*, Civ. No. 21-438, 2022 WL 788669, at *10 (D. Conn. Mar. 15, 2022). To satisfy the Rule 9(b) pleading standard a complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Mills v. Polar Molecular Corp*., 12 F.3d 1170, 1175 (2d Cir. 1993). *See Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004) (recognizing that "[t]he particularity

[6] Plaintiffs explicitly allege that "Defendants acted in concert with one another . . . to fraudulently convey false and misleading information concerning the SILTEX implants, and concealed the risks of serious adverse events associated with the SILTEX implants from Plaintiff Lory D'Addario, her physician, and the public." (SAC ¶ 23.)

requirement of Rule 9(b) serves to provide a defendant with fair notice of a plaintiff's claim . . . ."). Although Plaintiffs allege that Defendants acted fraudulently in misrepresenting the safety of their implants, they do not specify the statements that Plaintiffs contend were fraudulent, identify the speaker, state where and when the statements were made, and explain why the statements were fraudulent. The SAC therefore fails to satisfy Rule 9(b)'s pleading standard. *Mills*, 12 F.3d at 1175. For these reasons, this portion of Defendants' Motion will be granted, and Plaintiffs' negligent misrepresentation claims will be dismissed with prejudice.

3. Failure to Warn (Count I(C))

Courts evaluating a failure to warn claim engage in a three-step analysis. *See Karavitis v. Makita U.S.A., Inc*., 243 F. Supp. 3d 235, 252-53 (D. Conn. 2017). First, a plaintiff must satisfy the five elements governing all product liability claims.[7] *See id*. at 252. Second, the plaintiff must show that product instructions or warnings "were required, and . . . [that] they were adequate." *Id*. In that determination, the following factors are relevant: "(1) [t]he likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions." *Id*. at 252–53 (quoting Conn. Gen. Stat. § 52-572q(b)). Third, a plaintiff must establish that "if adequate warnings or instructions had been provided, the claimant would not have suffered the harm." *Id*. at 253 (quoting Conn. Gen. Stat. § 52-572q(c)).

[7] For product liability claims, the plaintiff must prove: (1) the defendant was engaged in the business of selling the product; (2) the product was in a defective condition unreasonably dangerous to the consumer or user; (3) the defect caused the injury for which compensation was sought; (4) the defect existed at the time of the sale; and (5) the product was expected to and did reach the consumer without substantial change in condition. *Karavitis*, 243 F. Supp. 3d at 249.

"Under the CPLA, a product seller is liable for a plaintiff's injuries when a product lacks adequate warnings directed to the person best positioned to keep the plaintiff from being hurt, and if the plaintiff would not have been injured if the warnings had been provided." *Klorczyk v. Sears, Roebuck & Co.*, Civ. No. 13-257, 2019 WL 1433645, at *13 (D. Conn. Mar. 29, 2019) (citing Conn. Gen. Stat. § 52-572q). "Warnings must specifically identify for the user the danger inherent in the product's use." *Id*. at *14 (quoting *Giglio v. Conn. Light & Power Co*., 180 Conn. 230, 237 (1980)); *see also Fraser v. Wyeth, Inc*., 992 F. Supp. 2d 68, 81 (D. Conn. 2014) ("An overly broad or confusing warning will not suffice to discharge a prescription drug manufacturer's duty to adequately warn a prescribing physician, nor is the mere mention or equivocal reference to a particular injury sufficient.")

Plaintiffs allege that Defendants failed "provide any warning of the risk of BIA-ALCL with its SILTEX breast implants to Plaintiff's plastic surgeon." (SAC ¶ 298.) Although Plaintiffs concede that the Siltex implants included a warning label and that warning label warned the risks of BIA-ALCL, "this label was not provided to [Plaintiffs' doctor]." (*Id.* ¶ 287.) Plaintiffs allege that Defendants failed to properly perform a number of studies required by the FDA as a condition for approving the PMA. (*Id*. ¶¶ 74–91.) Plaintiffs maintain that Defendants failed to attain the participation rates that would have been sufficient to allow for the identification of problems and adverse effects from long term use of the product. (*Id*. ¶ 93.) Since Defendants allegedly failed in this regard, Plaintiffs maintain that important adverse event data was never reported to the FDA. (*Id*. ¶ 223) ("Had Mentor properly performed its required studies and reported the multitude of captured adverse events, the FDA would have included the adverse events in the MAUDE database.")

Defendants argue that any failure to warn claim should be dismissed as a matter of law the moment that Plaintiffs conceded that Defendants provided a warning label with their Siltex implants because assuming that only Plaintiffs' Siltex implants were missing the warning is not plausible and takes the form of a bald assertion. (Moving Br. at 12–13.) Moreover, Plaintiffs' claim fails because Defendants did not have a duty to report adverse events to the FDA and even if it did, Plaintiffs did not allege a failure-to-report claim. (*Id.* at 14.)

Whether the implanting physician actually received the warning label that came with all the Siltex implants that warned of the risk of BIA-ALCL is a question of fact that cannot be decided at this point in the litigation. In construing the SAC in the light most favorable to Plaintiffs, they have sufficiently stated a failure to warn claim. First, Plaintiffs satisfy the five elements governing all product liability claims. Namely, they allege that the defendant was engaged in the business of selling the product (SAC ¶ 4); (2) the product was in a defective condition unreasonably dangerous to the consumer or user (*Id.* ¶¶ 2–3); (3) the defect caused the injury for which compensation was sought (*Id.* ¶ 111); (4) the defect existed at the time of the sale (*Id.* ¶ 251); and (5) the product was expected to and did reach the consumer without substantial change in condition (*Id.* ¶ 252). *Karavitis*, 243 F. Supp. 3d at 252. Next, Plaintiffs sufficiently allege that warning labels were required (SAC ¶¶ 282–98) and not provided to the person best positioned to keep the plaintiff from being hurt (*Id.* ¶ 287). *Karavitis*, 243 F. Supp. 3d at 252; *Klorczyk*, 2019 WL 1433645, at *13. Lastly, Plaintiffs establish that "if adequate warnings or instructions had been provided, the claimant would not have suffered the harm" (SAC ¶ 301–02). *Karavitis*, 243 F. Supp. 3d at 252. Accordingly, this portion of Defendants' Motion will be denied.

C. COUNT II—LOSS OF CONSORTIUM

Count II of the SAC alleges a loss of consortium. (SAC ¶¶ 324–28). A claim of loss of consortium is a derivative cause of action, and as such, "is dependent on the legal existence of the predicate action . . ." *Cavallaro v. Hospital of St Raphael*, 92 Conn. App. 59, 62, fn.5 (2005). As of October 1, 1979, the effective date of the CPLA, loss of consortium as between spouses had been recognized as a viable cause of action.

Plaintiffs allege that, as a result of the defective Siltex implants and subsequent diagnosis of BIA-ALCL, Plaintiff Lory D'Addario "was unable to perform activities she had previously commonly performed for the household, for the family, and for her own support," and "Plaintiff Peter D'Addario effectively lost the companionship and accompaniment of his wife." (SAC ¶¶ 325–26.) Defendants argue that "because all of Plaintiff's claims fail, her spouse's derivative loss-of-consortium claim also fails." (Moving Br. at 29.)

Plaintiffs' loss of consortium claim was dismissed previously because all of Plaintiffs' counts were dismissed and, as a derivative claim, the loss of consortium claim failed as a matter of law. Now, the survival of some of Plaintiffs' CPLA claims necessarily reinstates the derivative consortium claim. *Pappas v. Philip Morris, Inc.*, 915 F.3d 889, 898 (2d Cir. 2019).

D. STATUTE OF LIMITATIONS AND NOTICE OF CLAIMS

In their Moving Brief, Defendants argue that Plaintiffs' claims regarding the tissue expanders are time-barred because CPLA has a three-year statute of limitations for product liability claims. (Moving Br. at 24.) Plaintiffs clarify, however, that the inclusion of "tissue expanders is simply a clarification and extension of Plaintiffs' claims" and are not themselves new claims. (Reply at 29.) On its own review of the SAC, the Court also interprets the addition of references to tissue expanders to be additional supporting details for Plaintiffs' existing claims rather than

newly pled claims. These types of additions avoid statute of limitations issues because they relate back to the prior pleading under Rule 15(c). *See Siegel v. Converters Transp., Inc.,* 714 F.2d 213, 216 (2d Cir. 1983) (recognizing that Rule 15(c) is "to be liberally construed, particularly where an amendment does not allege a new cause of action but merely . . . makes defective allegations more definite and precise.") (citation omitted). As such, the Court concludes that inclusion of references to tissue expanders in the SAC does not run afoul of the statute of limitations. [8] Accordingly, the Court has considered the SAC's allegations regarding the permanent implants and the tissue expanders.

Defendants also argue that Plaintiffs do "not cure the group pleading deficiencies, which led this Court to dismiss her initial Complaint against Ethicon and Johnson & Johnson." (Moving Br. at 28.) Defendants continue by asserting that "the Complaint is still legally deficient because it lumps all defendants together in an undifferentiated fashion and fails to distinguish among their purported acts and omissions and their specific roles in bringing about Plaintiff's alleged injury." (*Id.*) Plaintiffs counter by arguing that their "allegations are appropriate to support the counts pled against each Defendant, therefore providing each Defendant adequate notice of the claims asserted against them. (Reply at 30.)

The Court agrees with Plaintiffs. The SAC alleges that Defendant Johnson & Johnson has admittedly owned Defendant Mentor since 2009 and lists Mentor as one of its own "medical device companies." (SAC ¶¶ 17–21, 226–233). The SAC also alleges that the FDA recognizes the relationship between Johnson & Johnson and Mentor is especially close, because the FDA's March 18, 2019, Warning Letter *was addressed to Alex Gorsky as the Chairman and CEO of Mentor*.

[8] In the alternative, the Court further concludes based on its review of the SAC, that the manufacture of the MemoryShape implants and CPX tissue expanders are the same "conduct, transaction, or occurrence" under Rule 15(c)(1)(B) because the products are manufactured in the same way with respect to their textured surface. (SAC ¶ 105.)

(*Id*. ¶¶ 81–83) (emphasis in original). At this stage in the litigation, Plaintiffs have done enough to give notice to each Defendant of the claims against them. Discovery will better address whether Plaintiffs named the correct parties in this suit.

IV. CONCLUSION

For the reasons stated above, the Court will GRANT the Motion with respect to Count I(E) and DENY the Motion with respect to Count I(A), (B), (C), (D), and Count II. An appropriate Order will follow.

Date: **January 18, 2023**

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE